

# **EXHIBIT B**

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

**IN RE VALSARTAN,  
LOSARTAN, AND IRBESARTAN  
PRODUCTS LIABILITY  
LITIGATION**

**MDL No. 2875**

**THIS DOCUMENT RELATES TO ALL  
CASES**

**HON. ROBERT B. KUGLER  
CIVIL NO. 19-2875 (RBK)**

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**DECLARATION OF RON NAJAFI, PH.D.**

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I, Ron Najafi, Ph.D., declare and state as follows:

1. I received B.S. and M.S. degrees in chemistry from University of San Francisco, and Ph.D. in chemistry from the University of California, Davis.
2. In 2011, I founded Najafi Pharma Inc., dba: Emery Pharma, where I currently serve as Chairman and CEO.
3. Emery Pharma is located at 1000 Atlantic Ave. Suite 110, Alameda, California 95401.
4. Emery Pharma is a full service contract research laboratory that performs analytical, bioanalytical chemistry, microbiology and cell biology services, custom synthesis and general research and development, and cGMP/GLP support to pharmaceutical companies.
5. Valisure, LLC had Emery Pharma test a few valsartan pills for the presence of N,N-Dimethylformamide (“DMF”) and N-nitrosodimethylamine (“NDMA”) in a blinded manner and report those results to Valisure, so that Valisure could compare Emery Pharma’s testing results with some results previously obtained by testing conducted by Valisure.

6. Conducting a study in a blinded manner means that certain information is withheld from Emery Pharma that has the potential to introduce bias, such as knowing the manufacturer of the pill being tested.
7. Emery Pharma was blinded to the manufacturer(s) of the valsartan pills tested for Valisure.
8. Emery Pharma was unaware which manufacturer's valsartan it was testing, or even how many manufacturer's valsartan it was testing.
9. Emery Pharma did not conduct any type of investigation into who manufactured the valsartan pills that Emery Pharma tested for Valisure, because doing so would defeat the purpose of being blinded.
10. Emery Pharma purposefully did not pay attention to any identifying features of the pills or document any identifying features of the pills, because doing so could unblind the study and introduce bias.
11. Emery Pharma did not record in any manner any of the identifying features of the valsartan pills that Emery Pharma tested for Valisure, such as by photograph or a written description.
12. Neither I nor anyone at Emery Pharma have any recollection of any of the identifying features of the valsartan pills that Emery Pharma tested for Valisure.
13. Emery Pharma is not in possession of Valisure's internal testing results that correspond to the valsartan pills Emery Pharma tested in a blinded manner for Valisure.
14. Valisure only gave Emery Pharma a limited number of valsartan pills to test for DMF and NDMA.
15. Emery Pharma tested every valsartan pill that was received from Valisure.

16. Emery Pharma is not still in possession of any of the valsartan pills received from Valisure, because the pills are destroyed via the process that Emery Pharma utilized to test the valsartan pills for DMF and NDMA.
17. Emery Pharma did not test any valsartan pills for the presence of N-nitrosodiethylamine (“NDEA”) for Valisure.
18. I have compared the limited valsartan testing results that Emery Pharma performed for Valisure with the numerous valsartan testing results in Valisure’s public citizen petition submitted on June 13, 2019.
19. None of the DMF and NDMA levels detected in a Valisure valsartan pill tested by Emery Pharma are remotely close to a DMF and NDMA level reported in Valisure’s citizen petition for any Novartis valsartan or Novartis valsartan-HCTZ.
20. Emery Pharma had no involvement with Valisure’s internal valsartan pill testing and Emery Pharma does not know the details of how Valisure calibrated, validated, or maintained their testing method.
21. All testing results obtained by Emery Pharma for Valisure are considered confidential work product and Emery Pharma cannot disclose the testing results without permission from Valisure.
22. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.



Date: April 25, 2022

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Ron Najafi, Ph.D.